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Guidance for the Reregistration of Pesticide Products Containing 1,3-Dichloropropene as the Active Ingredient

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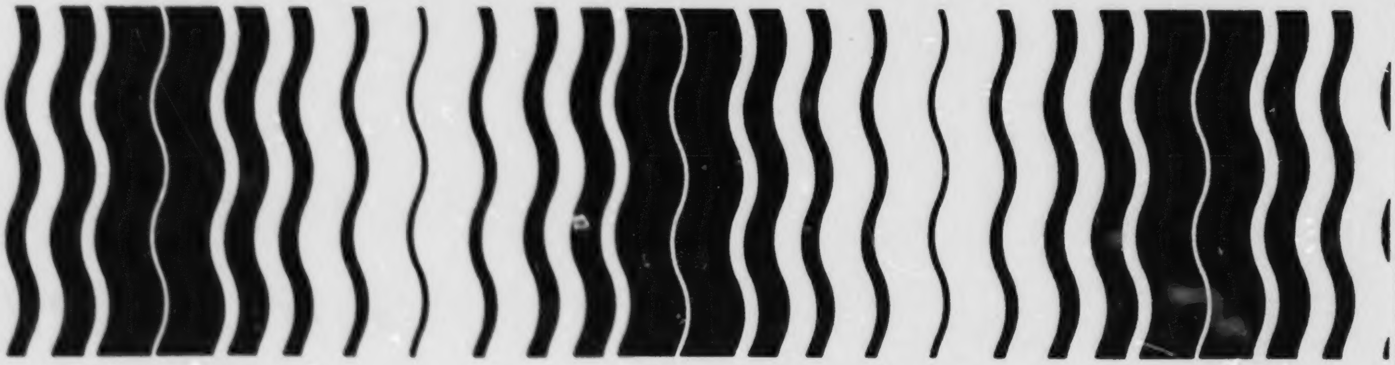

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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS (REGISTRATION STANDARD)

CONTAINING

1,3-DICHLOROPROPENE (TELONE II®)

AS THE ACTIVE INGREDIENT

CHEMICAL CODE: 029001

CAS: 542-75-6

CASE NUMBER: GS-0328

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

SEPTEMBER 18, 1986

TABLE OF CONTENTS

I. Introduction 1

II. Chemical Covered by this Standard . . . .
  A. Description of Chemical 4
  B. Use Profile 4

III. Agency Assessment . . . .
  A. Summary 5
  B. Preliminary Risk Assessment 7
  C. Other Science Findings 19
  D. Tolerance Reassessment 21

IV. Regulatory Position and Rationale. . . . .
  A. Regulatory Positions 22
  B. Criteria for Registration 25
  C. Acceptable Ranges and Limits 25
  D. Required Labeling 26

V. Products Subject to this Standard 29

VI. Requirement for Submission of Generic Data 31
  A. What are generic data? 31
  B. Who must submit generic data? 31
  C. What generic data must be submitted? 32
  D. How to comply with DCI requirements 32
  E. Procedures for requesting a change in protocol 34
  F. Procedures for requesting extensions of time 34
  G. Existing stocks provisions upon suspension or cancellation 35

VII. Requirement for Submission of Product-Specific Data . . 36

VIII. Requirement for Submission of Revised Labeling 37

IX. Instructions for Submission. 38
  A. Manufacturing use products (sole active) 38
  B. Manufacturing use products (multiple active) 39
  C. End use products 39
  D. Intrastate products 40
  E. Addresses 40

APPENDICES

I. DATA APPENDICES

Guide to Tables

Table A

Table B

II. LABELING APPENDICES

Summary of label requirements and table

40 CFR 162.10 Labeling Requirements

Physical/Chemical Hazards Labeling Statements

Storage Instructions

Pesticide Disposal Instructions

Container Disposal Instructions

III. USE INDEX APPENDIX

IV. BIBLIOGRAPHY APPENDICES

Guide to Bibliography

Bibliography

V. FORMS APPENDICES

EPA Form 8580-1	FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
EPA Form 8580-4	Product Specific Data Report
EPA Form 8570-27	Formulator's Exemption Statement

GLOSSARY FOR ACRONYMS

1. The AGENCY: U.S. Environmental Protection Agency/EPA
2. A.I.: Active Ingredient
3. DCI: Data Call-In Notice
4. EPs: End-use products
5. EUP: Experimental Use Permit
6. FIFRA: Federal Insecticide, Fungicide, Rodenticide Act (As Amended)
7. MPs: Manufacturing-use products
8. NTP: National Toxicology Program/Department of Human Health Services
9. NPDES Permit: National Pollutant Discharge Elimination System Permit
10. OES: Office of Endangered Species, U.S. Dept. of Interior
11. RAC's: Raw agricultural commodities
12. 40 CFR: Title 40 of the U.S. Code of Federal Regulations

I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient.

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[1] The science reviews are available upon request from the Information Services Section, Room 236, CM#2, 1921 Jefferson Davis Highway, Arlington, Va 22202, (Phone (703) 557-4453).
90 days after issuance, these reviews may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield Virginia 22161.

However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;
2. Modification of product labels;
3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;
4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;
5. Modification of uses or formulation types; or
6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data). In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, and B in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of chemical

The following chemical is covered by this Registration Standard:

Common name:	Dichloropropene
Chemical name:	1,3-Dichloropropene
CAS Number:	542-75-6
OPP (Shaughnessy) Number:	029001
Empirical Formula:	$C_3H_4Cl_2$
Trade names:	Telone II®, Dow Telone®
Year of Initial Registration:	1966
U.S. Producer:	Dow Chemical Company

Description of physical characteristics of chemical: 1,3-dichloropropene is a pale yellow liquid at room temperature. The empirical formula is $C_3H_4Cl_2$, and its molecular weight is 110.98. It is miscible in hydrocarbon solvents.

B. Use Profile

Type of Pesticide	: Broad spectrum soil fumigant
Pests Controlled	: Nematodes, plant diseases, insects and weeds.
Registered Uses	: Vegetables, field crops, citrus fruit trees, deciduous fruit & nut trees, bush and vine crops, ornamentals.
Predominant Uses	: Potatoes, tomatoes, carrots, tobacco, pineapples, and crucifers.
Mode of Activity	: Soil fumigation to control plant pests.
Formulation Types Registered	: 94% liquid formulation
Method of Application	: Mainly applied as preplant fumigant by chisel injection.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all data submitted to support the registration of 1,3-dichloropropene (Telone II®). Based on the review of these data, the Agency has reached the following conclusions. See Section B of this Part for a discussion of this review.

1. Oncogenicity

The Agency has categorized 1,3-dichloropropene as a probable human carcinogen. The data which justifies the Agency's position are:

a.) Chronic toxicity data indicate that 1,3-dichloropropene is oncogenic in both sexes of two species of test animals (rat and mouse);

b.) A 77 week subcutaneous injection study indicated increased incidence of fibrosarcomas at the site of injection;

c.) Several tests using procaryotic cells have indicated 1,3-dichloropropene to be a direct-acting mutagen; and

d.) 1,3-dichloropropene is structurally similar to other known oncogens (i.e. vinyl chloride), or known human oncogens.

Since 1,3-dichloropropene has met the risk criterion for oncogenicity in 40 CFR Section 154.7(a)(2), the Agency has placed this chemical in Special Review.

2. Dietary Exposure And Risk

1,3-dichloropropene has been registered for the uses (vegetable & field crops, citrus, fruit and nut trees) previously considered to be nonfood uses, and, thus, there are currently no tolerances established for 1,3-dichloropropene. In the past, the uses were considered nonfood uses when the pesticide was applied to the soil prior to planting and residues in the resulting crops were not expected.

Since the available data were inadequate to determine the presence of 1,3-dichloropropene residues in raw agricultural commodities (RAC's), a Data Call-In Notice has been sent to the registrant requesting appropriate residue and plant metabolism data. These data will be submitted to the Agency in approximately 12 months. Until the data are submitted and reviewed, a dietary risk assessment cannot be completed.

3. Worker Exposure And Risk

A risk assessment has been conducted for workers involved in the use of 1,3-dichloropropene. This analysis is based on exposure through 100% inhalation of the pesticide.

During the handling and application of 1,3-dichloropropene, dermal exposure is not expected because closed systems and protective clothing are required for the handling and application of the chemical. In case of equipment failure, dermal exposure is possible.

The Q_1* [the cancer potency estimate in terms of human equivalence] for 1,3-dichloropropene was calculated as $1.75 \times 10^{-1} \times (mg/kg/day)^{-1}$. (This Q_1* was generated using the oral oncogenicity study on rats). In order to assess potential human risk from exposure to this chemical, the average lifetime exposure in mg/kg/day is multiplied by the Q_1* of $1.75 \times 10^{-1} \times (mg/kg/day)^{-1}$. This is the formula which was used to estimate risk to workers exposed to 1,3-dichloropropene (Risk = Exposure x Q_1*).

Because the cancer potency is based upon oral studies whereas the exposure to workers is based on inhalation, the risks cited in Table 4 may not be true risk levels.

The registrant is conducting an oncogenicity study through the inhalation route which may refine the theoretical risk calculations cited in Table 4 for 1,3-dichloropropene.

B. PRELIMINARY RISK ANALYSIS

The Agency is concerned about the oncogenic potential of 1,3-dichloropropene and has assessed oncogenic risk to workers involved in applying, handling, and storing of this chemical. The Agency has determined that because of oncogenic effects in laboratory animals and potential exposure to workers, 1,3-dichloropropene meets or exceeds the risk criterion set forth in 40 CFR 154.7(a)(2). Therefore, the Agency has initiated a Special Review on 1,3-dichloropropene.

1. Oncogenicity Studies

The National Toxicology Program (NTP) conducted oncogenicity bioassays with orally administered Telone II (technical 1,3-dichloropropene) in rats and mice. In the rat oncogenicity study, 1,3-dichloropropene was observed to produce tumors of the forestomach, liver, mammary gland, thyroid gland, and adrenal gland in one or both sexes of animals. In the mouse oncogenicity study, 1,3-dichloropropene produced tumors in the forestomach, urinary bladder, lung, and liver in animals of one or both sexes. EPA evaluated this tumorigenicity data for compound-related effects, and developed a weight of the evidence position concerning the chemical's oncogenic activity.

a. Rat Oncogenicity Study.

In the NTP F344 rat study, Technical 1,3-dichloropropene was administered for 104 weeks at doses of 0, 25, and 50 mg/kg/day. A total of 77 animals/ sex were used for each dose group. The following incidence patterns of tumors suggestive of a compound-related effect were observed in male and/or female rats (Table 1).

Table 1. Incidence Patterns of Tumors Observed in Male and Female Rats Administered 1,3-dichloropropene

Tumor Site and Type	Sex	Dose (mg/kg/day) 0	25	50
Forestomach				
squamous cell papilloma	M F	1/77 (1%) 0/77 (0%)	1/77 (1%) 2/77 (3%)	13/77 (17%)* 8/77 (10%)*
squamous cell carcinoma	M	0/77 (1%)	0/77 (1%)	4/77 (5%)
squamous cell papilloma and carcinoma combined	M	1/77 (1%)	1/77 (1%)	17/77 (22%)*
Liver				
neoplastic nodules	M F	1/77 (1%) 6/75 (8%)	6/76 (8%) 8/77 (10%)	8/77 (10.4%)* 12/77 (16%)
hepatocellular carcinoma	M	0/77 (0%)	0/76 (0%)	1/77 (1.3%)
neoplastic nodules and carcinoma combined	M	1/77 (1%)	6/76 (8%)	9/77 (11.7%)*
Mammary Gland				
adenoma or fibroma	F	17/64 (27%)	23/63 (37%)	28/64 (44%)
Thyroid Gland				
follicular cell adenoma or carcinoma	F	0/75 (0%)	2/77 (3%)	5/77 (6%)
Adrenal Gland				
pheochromocytoma	M	4/77 (5%)	14/77 (18%)*	10/76 (13%)

* = $p < 0.05$ Fisher's Exact Test.

Forestomach: Statistically significant increases in squamous cell papillomas were found in high dose male and female rats, and significant increases in squamous cell papillomas and carcinomas (combined) were found in high dose male rats.

Liver: Statistically significant increases in neoplastic nodules, and in neoplastic nodules and carcinomas (combined) were found in high dose male rats.

Mammary Gland and Thyroid Gland: Positive trends for mammary gland adenomas or fibromas and for thyroid gland follicular cell adenomas or carcinomas were observed in female rats. None of the observed increases, however, were statistically significant. No historical control information on these tumor types was available.

Adrenal Gland: An elevated incidence of pheochromocytomas was observed in male rats receiving both doses. Only the tumor incidence seen at the lowest dose tested was statistically significant and a dose-response relationship was not evident. No historical information was available.

b. Mouse Oncogenicity Study.

In the NTP B6C3F1 mouse study, 1,3-dichloropropene (same technical formulation as used for the rat study) was administered for 104 weeks at doses of 0, 50, and 100 mg/kg/day. A total of 50 animals per sex were used for each dose group. This study has limited usefulness for two reasons: (1) animals were not randomized and (2) over 50 percent of the male control mice died near the end of the first year of the study. The following incidence patterns of tumors suggestive of a compound related effect were observed in male and/or female mice (Table 2).

Table 2. Incidence Patterns of Tumors in Male and/or Female Mice Administered 1,3-dichloropropene

Tumor Site and Type	Sex	Dose (mg/kg/day)			Historical Incidence
		0	50	100	
Forestomach					
squamous cell papilloma	M	0/50 (0%)	2/50 (4%)	3/50 (6%)	0.6%
	F	0/50 (0%)	1/50 (2%)	2/50 (4%)	0.3%
squamous cell carcinoma	M	0/50 (0%)	0/50 (0%)	0/50 (0%)	0.1%
	F	0/50 (0%)	0/50 (0%)	2/50 (4%)	0.1%
squamous cell papillomas and carcinomas combined	M	0/50 (0%)	2/50 (4%)	3/50 (6%)	0.6%
	F	0/50 (0%)	1/50 (2%)	4/50 (8%)	0.6%
Urinary Bladder					
transitional cell carcinomas	M	0/50 (0%)	0/50 (0%)	2/50 (4%)	0%
	F	0/50 (0%)	8/50 (16%)*	21/48 (44%)*	0%
Lung					
adenomas	M	1/50 (2%)	11/50 (22%)	9/50 (18%)	9.1%
	F	0/50 (0%)	3/50 (6%)	8/50 (16%)*	3.3%
carcinomas	M	0/50 (0%)	2/50 (4%)	3/50 (6%)	5.4%
	F	2/50 (4%)	1/50 (2%)	0/50 (0%)	1.5%
adenomas and carcinomas combined	M	1/50 (2%)	13/50 (26%)	12/50 (24%)	14.3%
	F	2/50 (4%)	4/50 (8%)	8/50 (16%)*	4.7%
Liver					
adenomas	M	1/50 (2%)	1/50 (2%)	3/50 (6%)	12.3%
	F	0/50 (0%)	5/50 (10%)	3/50 (6%)	4.0%
carcinomas	M	4/50 (8%)	6/50 (12%)	10/50 (20%)	20.5%
	F	1/50 (2%)	3/50 (6%)	0/50 (0%)	2.9%
adenomas and carcinomas combined	M	5/50 (10%)	7/50 (14%)	13/50 (26%)	31.4%
	F	1/50 (2%)	8/50 (16%)	3/50 (6%)	6.8%

* = $p < 0.05$, Fisher's Exact Test. The Fisher's Exact Test was not performed in males due to an insufficient number of males in the control group.

Forestomach: 1,3-dichloropropene produced the following changes in forestomach tumor pathology: (1) dose-related increases in squamous cell papillomas in male and female rats at 50 and 100 mg/kg/day; (2) an increase in squamous cell carcinomas in females at 100 mg/kg/day (no carcinomas were seen in male mice); and (3) dose-related increases in squamous cell adenomas and carcinomas (combined) in males and females at 50 and 100 mg/kg/day. The increased incidences of squamous cell papillomas and carcinomas appeared to be compound-related since neither tumor type was found in the concurrent control animals of either sex, and both tumors occurred only at very low incidences in the NTP historical control data provided.

Urinary Bladder: Increases in transitional cell carcinomas occurred in male mice at the 100 mg/kg/day dose level and in female mice at the 50 and 100 mg/kg/day dose levels (the increases in female were dose-related and statistically significant at both dose levels). No transitional cell carcinomas were found in either the concurrent control animals or in the NTP-provided historical control data for either sex of mice.

Lung: In males, an increase in the incidences (not strictly dose-related) of adenomas and of adenomas and carcinomas (combined) was found in the 50 and 100 mg/kg/day dose groups as compared to the concurrent control rates and the NTP provided historical control rates. In females, a dose-related increase in the incidences of adenomas and of adenomas and carcinomas (combined), was observed, and the oncogenic responses were statistically significant at the 100 mg/kg/day dose level.

c. Subcutaneous Injection

Thirty female Ha:ICR Swiss mice received weekly subcutaneous injections of cis-1,3-dichloropropene (3 mg/mouse) in 0.05 ml trioctanoin in the left flank. The duration of the test was 77 weeks. There was an increased incidence of fibrosarcomas at the site of injection. Six out of thirty mice treated with 1,3-dichloropropene developed the neoplasm as compared to 0/100 control animals.

2. Weight of the Evidence Regarding Oncogen Potential

The Agency considered the following facts regarding toxicology data on 1,3-dichloropropene to be of importance in a weight of evidence determination of oncogenic potential.

a. 1,3-dichloropropene when administered by gavage to rats at the highest dose level tested (50 mg/kg/day), is associated with significantly elevated incidences of (a) forestomach squamous cell papillomas in males and females, (b) forestomach squamous cell papillomas and carcinomas (combined) in males, and (c) liver neoplastic nodules in males. The increased incidence of forestomach tumors was accompanied by a positive trend in the incidences of forestomach basal cell hyperplasia in both male and female rats of both treated groups. There were also other tumors in rats, but the changes were either not statistically significant and/or did not occur in a dose-related manner.

b. 1,3-dichloropropene when administered by gavage to mice, is associated with elevated incidences of: (a) forestomach squamous cell papillomas in males and females, (b) forestomach squamous cell papillomas and carcinomas (combined) in females (c) urinary bladder transitional cell carcinomas in males and in females; (d) lung adenomas in males and females; and (e) lung adenomas and carcinomas (combined) for males.

c. EPA considered the possibility that stomach tumors produced by 1,3-dichloropropene in rats and mice in the NTP studies could have been attributable to the presence of a stabilizer, epichlorohydrin, in the technical 1,3-dichloropropene formulation. Epichlorohydrin has been demonstrated to produce similar types of forestomach neoplasms (squamous cell papillomas or carcinomas) in rats in non-NTP studies following oral administration (Konishi, et al., Gann 71:922-923, 1980; Wester et al., Report No. 627805 005, Rijtsinstituut voor volksgezonheid en millieuhygiene, 1984).

Two lines of evidence suggested that the oncogenic responses produced by 1,3-dichloropropene were not entirely due to the presence of epichlorohydrin. First, 1,3-dichloropropene produced neoplasms other than forestomach squamous cell papillomas and carcinomas in rats in the NTP study (e.g., increased liver neoplastic nodules and positive trends for mammary gland adenomas or fibromas and thyroid gland follicular cell adenomas and carcinomas); these tumor types were not reported to be produced by epichlorohydrin (Konishi et al., 1984).

Second, the doses of epichlorohydrin administered in the NTP studies were low (i.e., only 1% of the total daily doses of 1,3-dichloropropene). The maximum daily doses (given only 3x/week) of epichlorohydrin administered to rats and mice would not have exceeded 0.5 and 1.0 mg/kg, respectively. These doses are lower than those (approx. 37.5 to 75 mg/kg/day in drinking water and 2 mg/kg/day via gavage, given 5 days/ week) reported to cause forestomach tumors in the non-NTP studies (Konishi et al., 1980; Wester et al., 1984).

d. 1,3-dichloropropene, when administered by subcutaneous injection to Swiss mice, is associated with increased incidences of fibrosarcomas at the site of injection. The injections were given once a week for a duration of 77 weeks. Under the conditions of the experiment, it may be concluded that 1,3-dichloropropene increased the incidence of this neoplasm at the site of injection.

e. Positive results in mutagenicity tests support the oncogenicity findings. 1,3-dichloropropene has been found to be a direct acting mutagen in several tests utilizing prokaryotic cells. The compound produced positive results for gene mutation in several microbial strains (e.g., TA-1535, TA100, TA-98 and TA-1978) both in the presence and absence of metabolic activation, while negative results were obtained in a few other tests (e.g., reverse mutation assay with E. coli B/r Wp2, and mouse host mediated assay with S. typhimurium G46). In addition, 1,3dichloropropene produced positive results for DNA damage/repair in a nonactivated recombination assay using B. subtilis M45 and H17 strains.

f. Dichloropropene (cis-, trans-1,3-dichloropropene) bears a structural resemblance to several short chain halogenated hydrocarbon compounds that are known oncogens (e.g., ethylene dibromide and vinyl chloride monomer). In the case of ethylene dibromide, the same type of tumor response as produced by dichloropropene has been reported (IARC 15:195-209, 1977), namely forestomach squamous cell carcinoma in rats and mice after oral administration. The production of these forestomach tumors by ethylene dibromide occurred in the absence of epichlorohydrin as a possible contaminant. In the case of vinyl chloride, lung adenomas and/or adenocarcinoma have occurred in rats and mice following inhalation exposure (IARC 7:291-318, 1974; IARC 19:377-438, 1979). Similar pulmonary tumors are produced by 1,3-dichloropropene in rats and mice after oral administration.

3. Potency Estimate and Formula for Risk Estimation

The results from the two NTP chronic feeding studies in rats and mice indicate that increasing doses of 1,3-dichloropropene are associated with increasing tumor rates in both sexes of both species. It appears that male rats are the most sensitive in that increasing doses of the chemical produces significantly increasing numbers of either forestomach, liver, adrenal, or thyroid tumors.

The multistage model was used to determine the estimates of oncogenic potency of 1,3-dichloropropene in the two species of experimental animals. Review of the data indicates that male rats were the most sensitive to 1,3-dichloropropene in developing tumors of either the forestomach, liver, adrenal or thyroid gland. The estimated cancer potency (Q_1*) using these data was calculated to be 3.3 x 10^{-2} $(mg/kg/day)^{-1}$.

This potency for male rats is converted to human equivalence by (1) converting the diet of a rat in ppm to mg/kg/day and then (2) converting the rat dose in mg/kg/day to human equivalence by using a surface area correction:

$$\frac{(\text{Human weight})1/3}{(\text{Rat weight})}$$

The resulting Q_1* in human equivalence is 1.75 x 10^{-1} $(mg/kg/day)^{-1}$. In order to assess potential human risk from exposure to 1,3-dichloropropene, the average lifetime exposure in mg/kg/day is multiplied by the Q_1* of 1.75 x 10^{-1} $(mg/kg/day)^{-1}$. This is the formula which was used in the next section to estimate risk to workers exposed to 1,3-dichloropropene(Risk = Exposure x Q_1*).

4. Exposure Analysis and Risk Assessment

a. Inhalation Exposure

On August 22, 1985, Dow Chemical Company submitted exposure data from field monitoring reports from use of 1,3-dichloropropene.

The studies measured the worker exposure to 1,3-dichloropropene during several types of activities associated with use of the chemical. Nine valid studies were evaluated. Sampling were done in California and Florida. Table 3 is a summary of the data from the 9 valid studies. The exposure was estimated for the inhalation route only.

The data are arranged according to job function or time of field monitoring. From these data, an annual exposure estimate is calculated. The resulting estimate is in the last column of the table and is expressed in mg/kg/year. In the assessment, EPA assumed that the breathing rate is 29 liters per minute and a worker weighs 70 kg. The exposure in days/year is assumed to be for a private applicator: the exposure for a commercial applicator would be expected to be higher.

b. Non-Dietary Risk Assessment

The Agency has calculated the worker non-dietary potential oncogenic risk from exposure to 1,3-dichloropropene by multiplying the exposure in mg/kg/day for various activities by the potency or Q_1* of 1.75×10^{-1} $(mg/kg/day)^{-1}$. This represents a high level of oncogenic potency.

It is important to note that the exposure estimates summarized in Table 4 are only for the inhalation route. The measure of risk is based upon 100% inhalation exposure.

The risk estimates represent the upper 95% bound on the tumor response in the two laboratory animal experiments; the 95% bound is calculated primarily to account for uncertainties inherent in the animal experiments. The risks range from the order of 10^{-2} to 10^{-5} for the various work activities and are shown in the last column of Table 4.

Table 3. Inhalation Exposure Estimates for Workers Exposed to 1,3-dichloropropene Based on 9 Studies in California from Dow Chemical Company.

Activity	mg/1 Range of Exposure	Hourly Exposure @ 29 1/min	Hours/ Day*	mg/ day	Days/ year*	mg/ year	mg/kg/ year**
Bulk Transfer	0.006-0.3	10.4-522	0.5	5.2-261	2	10.4-522	0.15-7.5
Storage Areas	0.0005-0.06	0.87-104	8	7-832	2	14-1664	0.20-23.99
Loading	0.005-0.01	8.7-17	0.5	4-8.7	2	8-17.4	0.1-0.25
Highway Transport	0.00005	0.09	8	6.96	10	10	0.99
Applicator-Tractor	0.001-0.01	1.7-17	5	9-87	2	18-170	0.25-2.4
Post Treatment	0.0007-0.03	1.2-52	5	6-260	2	12-520	0.17-7.4
24 hrs	0-0.02	0-35	0	0	0	0	0
36 hrs	0-0.02	0-35	0	0	0	0	0
72 hrs	0	0	0	0	0	0	0
Downwind	0.002	3.48	2***	6.96	2	13.92	0.199

* Use practices vary. EPA estimated a total of about 10 hours total/yr for an average crop (This can vary: cotton-60 hrs/yr, sugar beets 23 hrs/yr, and vegetables about 9 hrs/year.) At 10 hrs/year for average farm, two days would be required. The highway transport is an estimate assuming a full day of driving and 10 days/year during treatment season. The post treatment concentration is a good estimate for the roller treatment which follows the treatment immediately to seal in the fumigant. EPA assumes no significant exposure occurs during aeration and planting as these operations are done 7-14 days after application.

** Based on a 70 kg man

*** Assuming limited high concentration downwind for two hours. Vapor pressure for 1,3-dichloropropene is such that it volatilizes rapidly into the air after soil injection. The down wind drift of this pesticide includes person(s) living adjacent to treated fields.

c. Dietary Exposure

The pesticide 1,3-dichloropropene is currently registered as a preplant nematicidal fumigant on soils to be applied to a number of raw agricultural commodities (e.g., vegetables, field crops, citrus, fruit and nut trees). These uses were registered as nonfood uses and thus there are currently no tolerances established for 1,3-dichloropropene. The uses registered were considered nonfood uses at the time because the pesticide was applied to the soil prior to planting and residues in the resulting crops were not expected.

Available residue data are inadequate to make a determination if residues of 1,3-dichloropropene, its metabolites, or formulation impurities will result in raw agricultural commodities as a result of use of 1,3-dichloropropene. A Data Call-In Notice was sent in June 1986, to the registrants, requesting appropriate residue and plant metabolism data. Plant metabolism data are to be received by March 1988, and residue data by March 1989.

Until these data are submitted and reviewed, an accurate dietary risk assessment cannot be carried out.

Table 4. Inhalation Exposure and Risk Estimates for Workers Exposed to 1,3-dichloropropene for Various Activities

Activity	EXPOSURE ESTIMATE					RISK ESTIMATE		
	(1) Observed Daily Exposure mg/kg/day		(2) Days Exposed per year	(3) *LADD = (1)x(2)x $\frac{(35 \text{ Work Yrs.})}{(70 \text{ Yr Life})}$ mg/kg/day		Upper Bound on Risk = (LADD x Q_1*) = [(3)x1.75×10^{-1} (mg/kg/day)$^{-1}$		Rounded Risk Range
	Min.	Max.		Low	High	Low	High	
Bulk Transfer	7.46×10^{-2}	3.73	2/365	2.04×10^{-4}	1.02×10^{-2}	3.6×10^{-5}	1.8×10^{-3}	10^{-5} - 10^{-3}
Storage Areas	9.94×10^{-2}	11.93	2/365	2.72×10^{-4}	3.27×10^{-2}	4.8×10^{-5}	5.7×10^{-3}	10^{-5} - 10^{-2}
Loading	6.21×10^{-2}	1.24×10^{-1}	2/365	1.70×10^{-4}	3.40×10^{-4}	3.0×10^{-5}	5.9×10^{-5}	10^{-5} - 10^{-4}
Highway Transport	9.94×10^{-3}		10/365	1.36×10^{-4}		2.4×10^{-5}		10^{-5}
Applicator Tractor	1.24×10^{-1}	1.24	2/365	3.40×10^{-4}	3.40×10^{-3}	5.9×10^{-5}	5.9×10^{-4}	10^{-5} - 10^{-3}
Post Treatment	8.7×10^{-2}	3.73	2/365	2.38×10^{-4}	1.02×10^{-2}	4.2×10^{-5}	1.8×10^{-3}	10^{-5} - 10^{-3}
24 Hours	0		0/365	0		0		0
36 Hours	0		0/365	0		0		0
72 Hours	0		0/365	0		0		0
Downwind **	9.94×10^{-2}		(2/365)	2.72×10^{-4}		4.8×10^{-5}		10^{-5} - 10^{-4}

* LADD = Lifetime Average Daily Dose

** Vapor pressure for 1,3-dichloropropene is such that it volatilizes rapidly into the air after soil injection. The down wind drift of this pesticide includes person(s) living adjacent to treated fields.

C. OTHER SCIENCE FINDINGS

1. 1,2-Dichloropropane Studies

The NTP has conducted two oncogenicity Studies with 1,2-dichloropropane, an impurity in 1,3-dichloropropene using rats and mice. EPA has completed a preliminary review of these studies. The results indicate that 1,2-dichloropropane is an oncogen and may pose a risk to humans. The summary within the NTP studies states that 1,2-dichloropropane is: (1) negative in male rats; (2) marginally positive for mammary tumors in female rats, but is designated as equivocal because of a high mortality rate; and (3) positive in male and female mice for liver tumors. The Agency's preliminary review indicates that the Q_1^* or oncogenic potency in terms of human equivalence is 6.3×10^{-2} $(mg/kg/day)^{-1}$ for males and 2.25×10^{-2} $(mg/kg/day)^{-1}$ for females.

However, the Agency believes that 1,2-dichloropropane is not of major toxicological concern for the following reasons: (1) 1,2-dichloropropane was an impurity in the chronic test formulations of 1,3-dichloropropene, presenting a minimal oncogenic risk when compared to the parent compound, and (2) its Q_1^* is ten times lower than the Q_1^* (1.75×10^{-1}) for 1,3-dichloropropene.

2. Teratology Studies

Two inhalation teratology studies were performed with 1,3-dichloropropene in rats and rabbits. In the rat study, no teratogenic effects were observed, although maternal toxicity occurred at all dose levels. Developmental toxicity (delayed ossification of vertebral centra) occurred at the highest dose (120 ppm). In the rabbit study maternal toxicity occurred at the 2 highest dose levels (60 ppm and 120 ppm) but no evidence of embryo fetotoxicity was apparent.

3. Reproductive Studies

A reproductive study with 1,3-dichloropropene is lacking at the present time. However, the registrant is conducting a two generation reproduction study in rats by the inhalation route. The study will be finalized in July 1987.

4. Metabolism Studies

Two limited metabolism studies in rats have been performed. In one study, orally administered radioactive (C^{14}) cis- and trans-1,3-dichloropropene was found to be excreted primarily in the urine over 4 days. Negligible amounts of radioactivity were found in the gastro-intestinal tract, skin, and carcass. No information on urinary or fecal metabolites was provided.

In the other study, orally administered radioactive cis-dichloropropene isomer yielded methyl-N-acetyl-S[(z)-3-chloroprop-2-enyl] cysteine as the main urinary metabolite. These two studies do not fulfill EPA's regulatory requirements for a metabolic study because additional data are required as to the disposition of the chemical.

5. Ground water Concerns

Available data indicate that 1,3-dichloropropene, the major component of technical Telone II®, does leach to ground water when it is present in the most sensitive environment (shallow ground water and sandy soils of low percentage organic matter in areas of high rainfall or irrigation). However, the relative hydrolytic instability of the parent compound would mitigate the potential for extensive contamination. Due to the high use rates involved (43 to 968 lbs ai/acre), all impurities and metabolites in the technical product are of concern.

There are very limited data on the chemical properties and environmental fate of 1,3-dichloropropene, and limited monitoring information available on the other components or degradates of this compound. Generally, data from monitoring studies focusing on 1,3-dichloropropene and 1,2-dichloropropane indicate frequent findings of 1,2-dichloropropane in a variety of environmental settings and less frequent findings of the major compound.

Data indicate that 1,2-dichloropropane, an impurity in technical Telone II, does have the potential to leach to ground water. The chemical structures of this and other impurities appear to be non-reactive and the compounds appear to be persistent and mobile. Information from the California State Water Resource Control Board shows that 1,2-dichloropropane is being found in both shallow and deep wells throughout the state. Monitoring data from Maryland, Massachusetts, New York, Connecticut and Washington also are positive for the chemical in ground water.

6. Acute Toxicity

1,3-dichloropropene is classified as Toxicity Category II for oral toxicity and primary eye irritation, and Toxicity Category III for dermal irritation.

7. Ecological Effects

Available toxicology data show that 1,3-dichloropropene is of low to moderate toxicity to birds and moderate toxicity to fish and aquatic invertebrates.

D. TOLERANCE ASSESSMENT

The Agency cannot conduct a tolerance assessment on 1,3-dichloropropene at this time because it previously considered all of the uses as non-food uses. No tolerances or exemptions from tolerances for residues of the chemical in or on food/feed commodities have been established in the United States.

Current residue data are inadequate to determine if residues of 1,3-dichloropropene, its metabolites, or impurities, will occur in raw agricultural commodities following its use. Data on the metabolism of 1,3-dichloropropene in crops and on residue storage stability are required. The additional data will be used to more fully assess possible residues in food and feed crops and may lead to additional data requirements in residue chemistry.

If these data indicate that residues of 1,3-dichloropropene are taken up by the crops, the establishment of tolerances will be necessary. The current toxicological studies do not meet the data requirements necessary to establish tolerances for this chemical. Therefore, the following toxicology tests may be required: chronic feeding studies using two species, oncogenicity studies by the oral route using two species, a two generation reproduction study by the oral route and teratology studies by the oral route using two species. Also, these data may be used to determine effects of dietary exposure through drinking water since the compound, its metabolites and impurities are potential ground water contaminants.

The Agency will not grant any pending or new tolerances for 1,3-dichloropropene until the required data are submitted and reviewed.

International Tolerances

Presently, there are no tolerances for residues of 1,3-dichloropropene in Canada, Mexico, or in the *Codex Alimentarius*.

IV. REGULATORY POSITION AND RATIONALE

A. POSITIONS AND RATIONALE

Based on the review and evaluation of all available data and other relevant information on 1,3-dichloropropene (Telone II®), the Agency has made the following determinations:

1. The Agency has placed 1,3-dichloropropene in Special Review because the chemical has met the risk criterion for oncogenicity in 40 CFR, Section 154.7(a)(2). The Agency has determined that the chemical may induce an oncogenic effect in humans and that this effect is of concern because of the potential worker/applicator exposure. (See Part III, Section B. for a discussion of the oncogenic potential and exposure estimates).

   Rationale: The Agency has categorized 1,3-dichloropropene as a probable human carcinogen. Available chronic toxicity data also show that this compound is oncogenic in both sexes of rats and mice. Interim regulatory measures in this registration standard will reduce risk to acceptable levels during the period necessary to complete the Special Review.

2. The Agency is classifying the 1,3-dichloropropene products for "Restricted Use". The products will be for retail sale and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by their certification.

   Rationale: The toxicological data and its oncogenicity indicate that 1,3-dichloropropene is extremely hazardous. The Agency believes that restricted use is necessary to protect mixer/loaders and applicators from inhalation exposure to this pesticide.

3. The Agency is continuing on an interim basis, the current reentry interval of 72 hours for the end-use products (EPs) of 1,3-dichloropropene.

   Rationale: There are no data on 1,3-dichloropropene to estimate reentry exposure to workers entering treated areas. In most cases, the Agency would set a reentry interval of 24 hours during which time reentry is prohibited without protective clothing. However, because 1,3-dichloropropene is extremely hazardous, the product is currently labeled with a 72 hour interval. The Agency will continue to use the 72 hour reentry interval until data are submitted to support a final interval.

   When the data are submitted, (40 CFR Sec. 158.140 Reentry Protection Data Requirements), the Agency will evaluate the exposure data and determine whether the 72 hour interval should be changed.

4. The Agency is continuing to require protective clothing and equipment specified on existing labeling. The type of protective clothing and equipment required includes cover alls gloves, heavy-duty footwear, safety goggles, and a mask or respirator approved for use with 1,3-dichloropropene.

Rationale: In order to minimize the exposure of workers to 1,3-dichloropropene, the Agency will require the protective clothing and equipment whenever high concentrations of 1,3-dichloropropene vapors might be expected (mixing/ loading, application and spillage sites).

5. The Agency will not grant any pending or new tolerances for 1,3-dichloropropene until the required data are submitted and reviewed. Current residue data are inadequate to determine if residues of the pesticide, its metabolites, or impurities will occur in raw agricultural commodities (RAC's) following its use.

Rationale: Previously the Agency considered the uses of 1,3-dichloropropene on RAC's as non-food uses. No tolerances or exemptions from tolerances for residues of 1,3-dichloropropene in or on food/feed commodities have been established.

6. The Agency is requiring environmental fate data including a protocol for ground water monitoring studies on technical Telone II®, its metabolites and impurities including 1,2-dichloropropane, in order to clarify its potential to contaminate ground water. If the required data indicate a high potential for ground water contamination, the Agency may place 1,3-dichloropropene in special review for this reason as well.

Rationale: Data indicate that 1,2-dichloropropane, an impurity in technical Telone II® reaches ground water under a variety of conditions. Due to the high use rates involved in the application of 1,3-dichloropropene (43 to 968 lbs. ai/acre), the Agency is concerned with all impurities in the technical product, and with metabolites that may be present in ground water.

1,3-dichloropropene, the major component of technical Telone II®, leaches to ground water when it is present in the most sensitive environment (shallow ground water and sandy soils of low percentage organic matter in areas of high rainfall or irrigation).

7. The Agency will require a cancer hazard warning statement on the label of 1,3-dichloropropene products. Refer to the labeling Section D. under Part IV. for wording.

   Rationale: The Agency has categorized the pesticide as a probable human carcinogen. Therefore, the cancer warning statement is intended to provide informed consent, and to encourage workers to comply with all of the directions for use of 1,3-dichloropropene products in order to minimize exposure to workers.

8. The Agency will not impose warning statements on MPs and EPs labels for non-target aquatic organisms and endangered species until the environmental fate data for 1,3-dichloropropene are received and reviewed.

   Rationale: 1,3-dichloropropene is low to moderately toxic to waterfowl and upland game birds. It is moderately toxic to coldwater fish, moderately toxic to warmwater fish and moderately toxic to freshwater invertebrates.

   Based upon currently available data, endangered species labeling statements are not warranted. If the environmental fate or other data indicate a potential hazard to endangered species, the Agency will request a consultation with the Office of Endangered Species, Department of the Interior.

9. While the data gaps are being filled and the Special Review is underway, currently registered MPs and EPs containing 1,3-dichloropropene as the sole active ingredient may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide and agree to develop additional data, as specified in the Data Appendices of this guidance document, in order to maintain existing registrations.

   Rationale: Under FIFRA, the Agency may choose not to cancel or withhold pesticide registration if data are missing or inadequate (See FIFRA sections 3(c)(2)(B) and 3(c)(7) or because a chemical is undergoing Special Review.

   Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION UNDER THIS DOCUMENT

To be subject to this guidance document, manufacturing-use products must meet the following conditions:

1. Contain 1,3-dichloropropene as the sole active ingredient and,
2. Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section E of this document.

Registration of products subject to this document must comply with all terms and conditions described in it, including commitment to fill data gaps on a schedule acceptable to EPA and consistent with that required of the present registrant. All registrants and applicants for registration under this document must follow the instructions contained in this document and complete and submit the appropriate forms within the specified time.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 94.0 percent 1,3-dichloropropene as the sole active ingredient. Each manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use products must be substantially similar to that in currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a new product and will not be registerable under this guidance document.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing 1,3-dichloropropene, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registrable under this Standard, manufacturing-use products containing 1,3-dichloropropene must be labeled for formulation only into end-use products only for the commodities listed below. The attached index entry lists all registered uses, as well as approved maximum application rates and frequencies.

1,3-dichloropropene is registered for use as a preplant soil fumigant on cotton, potatoes, tobacco, sugar beets, vegetables, apples, stone fruits, citrus, grapes, floral/turf and certain ornamental sites. For specific use patterns of 1,3-dichloropropene, please refer to the Use Index/Appendix.

D. REQUIRED LABELING

All manufacturing-use 1,3-dichloropropene products must bear appropriate labeling as specified in 40 CFR § 162.10, and below. The Labeling Appendices contain additional information on labeling requirements.

No pesticide product containing 1,3-dichloropropene may be released for shipment by a registrant or producer of that product after October 30, 1987, unless the product bears an Agency amended label which complies with the requirements of this Standard.

No pesticide product containing 1,3-dichloropropene may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received), delivered or offered to be delivered by any person after after October 30, 1988, unless the product bears an Agency amended label which complies with the requirements of this Standard.

The following information must appear on the labeling within the time limits specified above:

1. Ingredient Statement

The ingredient statement for all MPs and EPs must list the active ingredient as:

1,3-Dichloropropene .... %

2. Precautionary Statements

a. Manufacturing-Use Product Statements

All products intended for formulation into end-use products must bear the following statement:

"DANGER. Causes severe eye damage. May be fatal if inhaled, absorbed through skin, or swallowed. Do not get in eyes, on skin or on clothing. Wear chemical worker goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling, and before eating and smoking".

"Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency".

Cancer Hazard Warning Statement

" The use of this product may be hazardous to your health. This product contains 1,3-dichloropropene which has been determined to cause tumors in laboratory animals. Risks can be reduced by closely following the use directions and precautions, and by wearing protective clothing specified elsewhere on this label."

b. End Use Product Statements

1) The following human hazard statements must appear on all EPs labels:

"DANGER. Causes severe eye damage. May be fatal if inhaled, absorbed through skin, or swallowed. Do not get in eyes, on skin or on clothing. Wear chemical worker goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling, and before eating and smoking."

"RESTRICTED USE PESTICIDE"

"For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification."

Cancer Hazard Warning Statement

" The use of this product may be hazardous to your health. This product contains 1,3-dichloropropene which has been determined to cause tumors in laboratory animals. Risks can be reduced by closely following the use directions and precautions, and by wearing protective clothing specified elsewhere on this label."

2) The following environmental hazard statement must appear on all EPs:

"Do not contaminate water by cleaning of equipment or disposal of wastes. In case of spills, properly dispose of contaminated materials."

3) The following precautionary statements must appear on all EPs:

"Required clothing and equipment during the handling and application of 1,3-dichloropropene:"

"One-piece coveralls which have long sleeves and long pants constructed of laminated fabric as specified in the USDA/EPA Guide for Commercial Applicators."

"Liquid-proof hat such as a plastic hard hat with a plastic sweat band."

"Heavy-duty liquid proof (neoprene/synthetic) work gloves and boots."

"Any article worn while handling 1,3-dichloropropene must be washed before reusing. Immediately remove all clothing which has been drenched or has otherwise absorbed 1,3-dichloropropene from any spill. Dispose of contaminated clothing in a sanitary landfill by incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke."

Field Reentry

"Workers entering the treated area for 72 hours after application of 1,3-dichloropropene must wear protective clothing."

Storage And Disposal Statements

"Pesticide wastes are toxic. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for Guidance."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing 1,3-dichloropropene as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form   ), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing 1,3-dichloropropene in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing 1,3-dichloropropene as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing 1,3-dichloropropene either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Henry M. Jacoby
Product Manager (21)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE 1/

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity/Disclosure	TGAI	All	N/A	N/A	No	
61-2 - Description of Beginning Materials & Manufacturing Process	TGAI	All	N/A	N/A	Yes	6 months
61-3 - Discussion of Formation of Impurities	TGAI	All	N/A	N/A	Yes	6 months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	N/A	N/A	Yes	12 months
62-2 - Certification of Limits	TGAI	All	N/A	N/A	Yes	12 Months
62-3 - Analytical Method for Enforcement of Limits	TGAI	All	N/A	N/A	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	N/A	N/A	Yes	6 months
63-3 - Physical State	TGAI	All	N/A	N/A	Yes	6 months
63-4 - Odor	TGAI	All	N/A	N/A	Yes	6 months
63-5 - Melting Point	TGAI	All	No		No	N/A 3/
63-6 - Boiling Point	TGAI	All	N/A	N/A	Yes	6 months

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE 1/

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	N/A	N/A	Yes	6 months
63-8 - Solubility	TGAI or PAI	All	N/A	N/A	Yes	6 months
63-9 - Vapor Pressure	PAI	All	N/A	N/A	Yes	6 months
63-10 - Dissociation constant	PAI	All	N/A	N/A	Yes	6 months
63-11 - Octanol/water partition coefficient	PAI	All	N/A	N/A	Yes	6 months
63-12 - pH	PAI	All	N/A	N/A	Yes	6 months
63-13 - Stability	PAI	All	N/A	N/A	Yes	6 months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	All	No	-	No 4/	

1/ The technical product is not a registered manufacturing-use product.
2/ Not applicable. Although product chemistry data may been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.
3/ Not applicable because the technical is a liquid at room temperature.
4/ This compound does not require the submittal of samples at this time.

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	Yes	GS0328-001	No	
171-4 - Nature of Residue (Metabolism) - Plants	PAIRA	Partially	00040721, 00040722	Yes 1/	March 1988
- Livestock	PAIRA & Plant Metabolites	No	-	Reserved 2/	
171-4 - Residue Analytical Method - Plant residues	TGAI and Metabolites	Yes	00030385, 00033255 00033256, 00033257 00033258, 00033259 00033260, 00033262 00033263, 00033264 00039694, 00039695 00109291, 00109420 00109672, 00115214 00117045	No 3/	
- Animal residues	TGAI and Metabolites	No		No 3/	
171-4 - Storage Stability Data	TGAI and Metabolites	Partially	00033261	Yes 4/	March 1988

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue - Residue Studies					
- Crop Groups -- Crop Field Trials	TEP	Partially	00033255, 00033256 00033257, 00033258 00033259, 00033260 00033262, 00033263 00033264, 00039693 00039696, 00109672 00115214	Yes 5/	March 1989
-- Processed Food/Feed	EP	No		Reserved 6/	
-- Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	No		Reserved 6/	
- Potable Water	EP	No		Reserved 6/	
- Fish	EP	No		Reserved 6/	
- Irrigated Crops	EP	No		Reserved 6/	
- Food Handling	EP	No		Reserved 6/	
171-5 - Reduction of Residue	Residue of Concern	No		Reserved 7/	
171-7 - Reasonable Grounds in Support of Petition	--	No		Reserved 7/	

46

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

§158.125 Residue Chemistry - Continued

1/ Data are required depicting the distribution and metabolism of [^{14}C] 1,3-dichloropropene in soybeans and lettuce harvested at regular intervals which encompass seedling and mature growth stages following a single preplant soil injection application at 6 to 8 inches below the soil surface with the 94% formulation at a rate sufficiently high to permit complete characterization of ^{14}C-residues. If a significant proportion of the terminal residues are unextractable by the solvent(s) used, then analyses must include hydrolysis and reextraction of plant residues to determine the nature of bound or conjugated residues. Upon receipt of the data, an appropriate tolerance definition (parent compound plus all metabolites of toxicological concern) must be established with tolerances for residues in or on all food/feed crops for which uses of this pesticide are registered.

2/ If real residues are found in feed-commodities, data depicting the metabolism of 1,3-dichloropropene in ruminants and poultry will be required. If transfer of residues of 1,3-dichloropropene to ruminants and poultry tissue occur, then appropriate feeding studies with these animals will be required.

3/ Additional data may be required depending on residues determined in the metabolism testing.

4/ Available data show that the storage stability of 1,3-dichloropropene in or on frozen plant samples is poor after 75 days in frozen storage. The following data are required: the storage conditions and intervals from harvest to analysis of all plant samples used to obtain all residue data in this standard. The data must be accompanied by stability data depicting the percent decline of all residues of concern in plant samples stored under the specified conditions.

5/ Available data are not adequate to determine the magnitude of terminal residues of 1,3-dichloropropene in or on food/feed commodities because (i) dosage rates were unclear, (ii) storage stability was poor, and (iii) much of the data were generated on foreign sites. The following data will be required (if the radiolabeled metabolism studies reveal detectible residues): representative commodities from each crop group listed in 40 CFR 180.34 (with the exception of herbs and spices); asparagus, okra, cotton, flax, hops, peanuts, safflower, sugarcane, olives, persimmons, pineapple, and pomegranates must be treated preplant at representative geographic locations with the 94% formulation according to the label directions at the maximum registered rate. Samples of all raw agricultural commodities from each crop must be collected at the shortest interval after planting in which they could be used for food or feed purposes. Since frozen storage stability is poor, samples must be analyzed as soon as possible following collection. Tolerances reflecting maximum expected residue levels must be proposed or, if no measurable residues are detected, the limits of detection must be proposed.

6/ These requirements are reserved until such time as data indicate that the magnitude of residues of 1,3-dichloropropene at these sites pose concerns.

7/ This requirement is reserved until such time as data indicate that residues of 1,3-dichloropropene are present in food/feed commodities.

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C	Yes	Acc. 0261118	No	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B,C	No	-	No 1/	
161-3 - On soil	TGAI or PAIRA	A,B,C	No	-	No 1/	
161-4 - In Air	TGAI or PAIRA	A,B,C	No	-	Yes	9 months
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No	-	Yes	27 months
162-2 - Anaerobic Soil	TGAI or PAIRA	A,C	No		No 2/	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	No	-	Yes	27 months
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No	-	Yes	27 months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A,B,C	No	-	Yes	12 months
163-2 - Volatility (Lab)	TEP		No		No 1/	
163-3 - Volatility (Field)	TEP		No		Yes 3/	27 months

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	No	-	Yes 3/	27 months
164-2 - Aquatic (Sediment)	TEP	C	No	-	Yes	27 months
164-3 - Forestry	TEP	-	No		No 5/	
164-4 - Combination and Tank Mixes	TEP		No		No 4/	
164-5 - Soil, Long-term	TEP	A,B,C	No		Reserved 6/	50 months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A,C	No	-	Yes	39 months
165-2 - Rotational Crops (Field)	TEP	A,C	No		Reserved 7/	
165-3 - Irrigated Crops	TEP	A,B,C	No		No 5/	
165-4 - In Fish	TGAI or PAIRA	A,B,C	No		No 5/	
165-5 - In Aquatic Non-Target Organisms	TEP	A,B,C	No		No 5/	
SPECIAL STUDIES:						
- Ground Water Monitoring	PAIRA	A,B,C	No	-	Yes 8/	15 months

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

§158.130 Environmental Fate - Continued

1/ Data are not required because of application of this pesticide by soil injection.
2/ Data are not required if acceptable anaerobic aquatic metabolism data are submitted.
3/ Prior to initiating test, submit protocol by April 30, 1987 to the Agency for review and approval. Combine testing for volatility and dissipation from soil on three or more soil types by continuously sampling air near the surface of treated areas. Report residues of 1,3-dichloropropene and 1,2-dichloropropane, beginning at 0, and 12 hours, and 1, 3, 4, 7, 14, and 21 days or until the dissipation curve is established.
4/ Data on 1,3-dichloropropene in combination and tank mixes are not addressed in this Guidance Document.
5/ Data are not required in accordance with the current use patterns of this pesticide.
6/ Data may be required unless residues in the soil dissipate to less than 50% prior to subsequent treatment.
7/ Data may be required, depending on results of the confined crop studies.

8/ Special studies: the registrant will be required to submit protocols by April 30, 1987 to monitor ground water in order to verify that 1,3-dichloropropene including its metabolites and impurities, is a contaminant of ground water supplies. The registrant(s) must take the following steps by April 30, 1987: (a) they must provide the Agency with a map outlining sales of technical Telone II® on a county basis for the entire country, (b) they must provide a 2 to 3 page description of the soil types, agricultural practice and climate for those geographical areas that are typically associated with sale of the pesticide. The protocol (report and descriptions) can be kept manageable by describing one area as a representative of several areas.

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B,C	No		No 3/	
133-1 - Soil Dissipation	TEP	A,B,C	Partially	Acc. 259158	Yes 1/	27 Months
133-3 - Dermal Exposure	TEP	A,B,C	No		Yes 1/2/	27 Months
133-4 - Inhalation Exposure	TEP	A,B,C	Partially	Acc. 259158	Yes 1/2/	27 Months
§158.142 Spray Drift	TEP	A,B,C	3/			

1/ For each site, registrant must propose an acceptable entry interval based upon the following:
- Tasks that require reentry into a treated area,
- Air concentrations of 1,3-dichloropropene at the time of reentry,
- Residues of 1,3-dichloropropene in or on the soil where worker exposure to the treated soil may likely occur.

2/ The Agency requires data on quantitative permeation and breakthrough time on various materials used for protective clothing and equipment (gloves, boots, respirator hoses, [illegible]ieces, etc.) for the formulated product(s). If quantitative data are not available, then appropriate p[illegible]lity studies should be conducted. (Note the Agency received from the registrant on 7/9/86, data [Acc. 263741] on chemical protective clothing materials. These data are being reviewed by the Agency.)

3/ 1,3-dichloropropene is not applied by foliar/above ground application but it is soil injected.

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,H	Yes	00039683, 00039686	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,H	No	-	Yes	9 months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,H	No	-	Yes	9 months
81-4 - Primary Eye Irritation	TGAI	A,B,H	Yes	00039676	No	
81-5 - Primary Skin Irritation	TGAI	A,B,H	Yes	00039676	No	
81-6 - Dermal Sensitization	TGAI	A,B,H	No	-	Yes	9 months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B,H	No		No 1/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and - Non-rodent (Dog)	TGAI	A,B,H	No	-	Reserved 2/ Reserved 2/	
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,H	No	-	Yes 3/	12 months
82-3 - 90-Day Dermal - Rabbit	TGAI	A,B,H	No		No 11/	
82-4 - 90-Day Inhalation: - Rat	TGAI	A,B,H	No	-	Yes 4/	
82-5 - 90-Day Neurotoxicity: - Hen -Mammal	TGAI	A,B,H	No		No 5/	

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species: - Rodent, and	TGAI	A,B,H	No	-	Yes 6/	July 1988
- Non-rodent (Dog)	TGAI	A,B,H	No	-	Yes 6/	
83-2 - Oncogenicity - 2 species: - Rat (preferred), and	TGAI	A,B,H	Partially	00146469	Yes 7/	July 1988
- Mouse (preferred)	TGAI	A,B,H	Partially	00146469	Yes 7/	July 1988
83-3 - Teratogenicity - 2 species: - Rat	TGAI	A,B,H	Yes	Acc.0260474	No 8/	
- Rabbit	TGAI	A,B,H	Yes	Acc.0260474	No 8/	
83-4 - Reproduction - Rat 2-generation	TGAI	A,B,H	No	-	Yes 9/	July 1987
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A, B	Yes	00039687, 00061059 00119179, 00120906	No	
84-2 - Structural Chromosomal Aberration	TGAI	A, B	No	-	Yes 10/	12 months
84-4 - Other Genotoxic Effects	TGAI	A, B	Yes	00039688	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B	No	-	Yes	24 months
85-2 - Dermal Penetration	Choice	A,B	No		No 11/	
86-1 - Domestic Animal Safety	Choice	A,B	No		No 11/	

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

§158.135 Toxicology - Continued

1/ 1,3-dichloropropene is not an organophosphate and is not structurally related to a substance that causes delayed neurotoxicity.

2/ Intended uses of the product may result in residues in food crops.

3/ Repeated human exposure may be via skin contact.

4/ Not required if chronic inhalation data are submitted (studies in progress).

5/ Neuropathy/neurotoxicity not observed in acute oral, dermal, or inhalation studies. 1,3-dichloropropene is not an organophosphate, carbamate, or structurally related to an agent that causes neurotoxicity.

6/ The registrant reported that chronic inhalation studies in rats and mice are in progress. Final reports are expected in July 1988. However, it should be noted that if residues of 1,3-dichloropropene are found in food/feed commodities, chronic feeding studies in rodent and dog may be required.

7/ The registrant reported that 2 year inhalation/oncogenicity studies in rats and mice are in progress. Final reports are expected in July 1988. However, it should be noted that if residues of 1,3-dichloropropene are found in food/feed commodities, oncogenicity feeding studies in rat and mouse may be required.

8/ If residues of 1,3-dichloropropene are found in food/feed commodities, teratology studies by oral route in the rat and rabbit may be required.

9/ An inhalation 2-generation reproduction study in rats is in progress. The final report is expected in July 1988. If residues of 1,3-dichloropropene are found in food/feed commodities, a 2-generation rat study by gavage may be required.

10/ These mutagenicity tests are required:
  a. In vitro/in vivo primary hepatocyte repair for UDS testing both in vivo and in vitro exposure of cells to 1,3-dichloropropene.
  b. In vivo cytogenetics test for chromosomal aberrations using bone marrow preparations of rats,

11/ The guidelines and use patterns indicate that these data are not required.

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,C	Yes	00118938	No	
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird, and	TGAI	A,B,C	Yes	00120908	No	
- Waterfowl	TGAI	A,B,C	Yes	GS0328-002 (STEODI03)	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B,C	No		No 1/	
71-4 - Avian Reproduction						
- Upland Game Bird, and	TGAI	A,B,C	No		No 1/	
- Waterfowl	TGAI	A,B,C	No		No 1/	
71-5 - Simulated Field Testing						
- Mammals, and	TEP	A,B,C	No		No 1/	
- Birds	TEP	A,B,C	No		No 1/	
- Actual Field Testing						
- Mammals, and	TEP	A,B,C	No		No 1/	
- Birds	TEP	A,B,C	No		No 1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity - Warmwater Fish Species,	TGAI	A,B,C	Yes	00039692	No	
	TEP	A,B,C	No		No 1/	
- Coldwater Fish Species	TGAI	A,B,C	Yes	00039692	No	
	TEP	A,B,C	No		No 1/	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,C	Partially	00117044	No 1/	
	TEP	A,B,C	No		No 1/	
72-3 - Acute Toxicity to Estuarine and Marine Organisms - Marine Fish	TGAI	A,B,C			No 1/	
- Mollusk	TGAI	A,B,C	No		No 1/	
- Shrimp	TGAI	A,B,C	No		No 1/	
72-4 - Fish Early Life Stage, and	TGAI	A,B,C	No		No 1/	
- Aquatic Invertebrate Life-Cycle	TGAI	A,B,C	No		No 1/	
72-5 - Fish - Life-Cycle	TGAI	A,B,C	No		No 1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A,B,C				
- Crustacean			No		No 1/	
- Fish			No		No 1/	
- Insect Nymph			No		No 1/	
- Mollusk			No		No 1/	
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A,B,C	No		No 1/	
- Actual Field Testing -Aquatic Organisms	TEP	A,B,C	No		No 1/	

……

§158.145 Wildlife and Aquatic Organisms - Continued

1/ The requirements for additional aquatic invertebrate testing of 1,3-dichloropropene have been waived because this pesticide is a soil injected fumigant; fish data and a freshwater invertebrate study indicate moderate toxicity.

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B,G	Yes	00028772	No	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,G	No		No 1/	
141-4 - Honey bee subacute feeding study	(Reserved) 2/					
141-5 - Field testing for pollinators	TEP	A,B,G	No		No 1/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved) 3/					
142-1 - Aquatic insect life-cycle study	(Reserved) 3/					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved) 3/					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved) 3/					

TABLE A
GENERIC DATA REQUIREMENTS FOR 1,3-DICHLORORPROPENE

§158.155 Nontarget Insects

1/ Data from the acute contact study on 1,3-dichloropropene indicate low toxicity to bees, therefore no further testing is required.

2/ Requirements are reserved pending development of test methodology.

3/ Reserved pending Agency's decision as to whether data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 1,3-DICHLOROPROPENE 1/

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?2	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity/Disclosure	TGAI	All	N/A	N/A	No	
61-2 - Description of Beginning Materials & Manufacturing Process	TGAI	All	N/A	N/A	Yes	6 months
61-3 - Discussion of Formation of Impurities	TGAI	All	N/A	N/A	Yes	6 months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	N/A	N/A	Yes	12 months
62-2 - Certification of Limits	TGAI	All	N/A	N/A	Yes	12 Months
62-3 - Analytical Method for Enforcement of Limits	TGAI	All	N/A	N/A	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	N/A	N/A	Yes	6 months
63-3 - Physical State	TGAI	All	N/A	N/A	Yes	6 months
63-4 - Odor	TGAI	All	N/A	N/A	Yes	6 months
63-5 - Melting Point	TGAI	All	No		No	N/A 3/
63-6 - Boiling Point	TGAI	All	N/A	N/A	Yes	6 months

61

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 1,3-DICHLOROPROPENE 1/

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	N/A	N/A	Yes	6 months
63-12 - pH	MP	All	N/A	N/A	Yes	6 months
63-14 - Oxidizing/Reducing Action	MP	All	N/A	N/A	Yes	6 months
63-15 - Flammability	MP	All	N/A	N/A	Yes	6 months
63-16 - Explodability	MP	All	N/A	N/A	Yes	6 months
63-17 - Storage Stability	MP	All	N/A	N/A	Yes	6 months
63-18 - Viscosity	MP	All	N/A	N/A	Yes	6 months
63-19 - Miscibility	MP	All	N/A	N/A	Yes	6 months
63-20 - Corrosion Characteristics	MP	All	N/A	N/A	Yes	6 months
Other Requirements:						
64- 1 - Submittal of samples	MP	All	No		No 4/	

1/ The technical product is not a registered manufacturing-use product.

2/ Not applicable. Although product chemistry data may been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

3/ Not applicable because the technical is a liquid at room temperature.

4/ This compound does not require the submittal of samples at this time.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING 1,3-DICHLOROPROPENE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Addtl Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A,B,H	Yes	00039683, 00039686	No	
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B,H	No	-	Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	A,B,H	No	-	Yes	9 Months
81-4 - Primary Eye Irritation	MP	A,B,H	Yes	00039676	No	
81-5 - Primary Skin Irritation	MP	A,B,H	Yes	00039676	No	
81-6 - Dermal Sensitization	MP	A,B,H	No	-	Yes	9 Months

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL REQUIRED	PLACEMENT ON LABEL PREFERRED	COMMENTS
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front pan	Directly below e main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms where appropriate. Both terms shall [illegible] in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000.	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for-use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with differen registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposa

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potenti or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposa statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] / Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________________ Date ______________________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute [illegible] toxicity rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

Form 8580-6 (10-82)

FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ______________ Product Name ______________________

Applicant's Name and Address ______________________________________

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): ______________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated __________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ______________________

Date ______________ Title ______________________

EPA Form (April 1985)

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1,3-DICHLOROPROPENE

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

Reproduced from best available copy.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
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MRID	CITATION
00028772	Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1973) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. Rev. By Univ. of California--Riverside, Dept. of Entomology. Riverside, Calif.: UC, Agricultural Extension Service. (Also in unpublished submission received Apr 2, 1980 under 464-556; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242149-Z)
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00039692	Bentley, R.E. (1975) Acute Toxicity of M-3993 to Bluegill (Lepomis macrochirus) and Rainbow Trout (Salmo gairdneri). (Unpublished study received Jul 22, 1980 under 464EX-63; prepared by Bionomics, EG&G, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-T)
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00039694	Glas, R.D. (1980) Determination of Resudies [sic] of Cis- and Trans- 1,3-Dichloropropene in Fruit: ACR 80.9. Method dated Jul 9, 1980. (Unpublished study received Jul 22, 1980 under 464-EX-63; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 099515-X)
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00109420	Shell Development Co. (1981) Residue Determination of 1,2-dichloropropane and the Z and E Isomers of 1,3-dichloropropene in Agricultural Commodities, Soil and Water: Capillary GLC/Hall Electrolytic Conductivity Detector Method: MMS-R-505-2. (Unpublished study received Jan 15, 1982 under 201-253; CDL: 246672-A)
00109672	Shell Chemical Co. (1978) D-D Crop Residue and Analytic Methods: Volume III. (Compilation; unpublished study received Aug 30, 1978 under 201-119; CDL:235253-A)

OFFICE OF PESTICIDE PROGRAMS
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MRID CITATION

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00115214 Dow Chemical U.S.A. (1982) Residue Data, Where Pertinent, on (a) Food or Feed Commodities; (b) Non-food Crops Such as Tobacco; and (c) Foliage or Other Sites Which May Relate to Worker Hazard or Adverse Effects on the Environment. Include a Description of the Analytical Method(s) Used and a Summary of the Data. (Compilation; unpublished study received Sep 22, 1982 under 464-EX-63; CDL:248406-B)

00117044 LeBlanc, G. (1980) Acute toxicity of priority pollutants to water flea (Daphnia magna). Bull. Environm. Contam. Toxicol. 24:684-691. (Also in unpublished submission received Sep 22, 1982 under 464-EX-63; submitted by Dow Chemical U.S.A., Midland, MI; CDL:248415-F)

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00119178 Dow Chemical U.S.A. (1977) Telone II Soil Fumigant: Product Chemistry. (Compilation; unpublished study received Mar 23, 1977 under 464-511; CDL:228769-A)

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EPA Compendium of Acceptable Uses

1,3-DICHLOROPROPENE

TABLE OF CONTENTS

Site Name	Page
TERRESTRIAL FOOD CROP	3
(Agricultural Crops)	3
Caneberries	6
Citrus Fruits	6
Citrus Fruits	6
Deciduous Fruit Trees	6
Field Crops	7
Mint	8
Nut Trees	6
Peach	9
Pineapple	9
Potato (white)	9
Small Fruits	7
Strawberry	10
Sugar Beets	10
Vegetables	7
Vine Fruits	6
TERRESTRIAL NON-FOOD CROP	11
(Agricultural Crops)	11
Tobacco	11
(Ornamental Plants and Forest Trees)	11
Forest Trees	11
Ornamental Flowering Plants	12
Ornamental Grasses	12
Ornamental Plants	12
Ornamental Plants (deep rooted)	11
Ornamental and/or Shade Trees	11
Ornamental Turf	12

c029001

1,3-DICHLOROPROPENE*

TYPE PESTICIDE: Nematicide, Insecticide, Fungicide, Herbicide

FORMULATIONS: RTU (9.5 lb/gal or 94%)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Apply only as a preplant soil fumigation treatment. Telone II is corrosive under certain conditions - flush all applicators with fuel oil or kerosene immediately after use. Do not use water. Do not use containers, pumps, or other transfer equipment made of aluminum, magnesium or their alloys, as under certain conditions Telone II may be severely corrosive to such metals.

Fumigation may temporarily raise the level of ammonia nitrogen and soluble salts in the soil. This is most likely to occur when heavy rates of fertilizer and fumigant are applied to soils that are either cold, wet, acid, or high in organic matter. To avoid injury to plant roots, fertilize as indicated by soil tests made after fumigation. To avoid ammonia injury or nitrate starvation, or both, to crops on high organic soils do not use fertilizers containing ammonium salts and use only fertilizers containing nitrates, until after the crop is well established and the soil temperature is above 65 F (18.3 C).

Certain crops including cotton, sugarcane, and pineapple are tolerant to ammonia and the above rule does not apply to them. When using high rates of Telone II as required by certain state nursery regulations, liming of highly acid soils before fumigation may stimulate nitrification and reduce the possibility of ammonia toxicity. Certain nursery crops such as citrus seedings, *Cornus* sp., *Crataegus* sp., spruce, and vegetable crops such as cauliflower have shown evidence of phosphorous deficiency following fumigation. To avoid this possible effect, it is suggested that additional phosphate fertilizer be used on soils where experience indicates a deficiency may occur.

Precautionary Statements: DANGER. Corrosive, causes irreversible eye damage. May be fatal if inhaled, absorbed through skin, or swallowed. Do not get in eyes, on skin or on clothing. Wear chemical worker goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling, and before eating and smoking.

Required clothing and equipment for mixing/loading and applying 1,3-dichloropropene: One-piece coveralls which have long sleeves and long pants constructed of laminated fabric as specified in the USDA/EPA Guide for Commercial Applicators; liquid-proof hat such as a plastic hard hat with a plastic sweat band; heavy-duty liquid proof (neoprene/synthetic) work gloves and boots. Any article worn while handling 1,3-dichloropropene must be washed before reusing. Immediately remove all clothing which has been drenched or has otherwise absorbed 1,3-dichloropropene from any spill. Dispose contaminated clothing in a sanitary landfill, by incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

*Telone II

Issued: 3-06-84
Provisional Update: 8-29-86

GENERAL WARNINGS AND LIMITATIONS (continued)

NIOSH- or MESA-approved respiratory protection should be worn when Telone II liquid soil fumigant is exposed to the atmosphere or when conducting operations which vent to the atmosphere. A NIOSH- or MESA-approved half-face respirator with chemical worker's goggles or full-face respirators shall be used during small spills, repairs, calibrations, transfers, sampling and when working in poorly ventilated areas. When in use cannisters or cartridges shall be replaced daily or sooner if specified by manufacturer or at first sign of odor breakthrough, whichever comes first. NIOSH-approved cartridges, such as a Welsh 7400-IL, will be adequate for short-term situations such as listed above.

Where very high concentrations of vapors might be expected (such as large spills in poorly ventilated areas) a self-contained or air-supplied respirator should be used.

Field Reentry Statement: Workers entering the treated area for 72 hours after application of 1,3-dichloropropene must wear protective clothing.

Definition of Terms:
a.i. - active ingredient

1,3-DICHLOROPROPENE

Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Apply as a preplant soil treatment to control plant parasite nematodes [root-knot, meadow (lesion), citrus, cyst formers (golden, sugar beet, soybean), burrowing, ring, spiral, sting, pin, stubby root, stylet, dagger], wireworms, and symphylans. Apply to land to be planted with the following crops:

Vegetable Crops:

asparagus
beans
beets
blackeyed peas
broccoli
brussels sprouts
cabbage
cantaloupe
carrots
cauliflower
celery
collards
corn
cowpeas
cucumbers
egg plant
endive
garlic
horseradish
kale
kohlrabi
leeks
lettuce
melons
mustard greens
okra
onions
parsnips
peas
peppers
pimentoes
potatoes
pumpkins
radishes
rutabagas
salsify
shallots
spinach
squash (summer)
squash (winter)
sweet potatoes
swiss chard
tomatoes
turnips
watermelons

Field Crops:

alfalfa
barley
birdsfoot trefoil
buckwheat
clover
corn
cotton
flax
grasses
hops
lespedeza
millet
milo
mint
oats
pasture grass
peanuts
popcorn
rice
rye
safflower
sorghum
soybeans
sugar beets
sugarcane
tobacco
vetch
wheat

Citrus Fruit Tree Planting Sites:

grapefruit
kumquats
lemons
limes
oranges
tangerines
tangelos

Deciduous Fruit and Nut Tree Planting Sites:

almonds
apples
apricots
cashews nuts
cherries
chestnuts
dates
figs
filberts
hazelnuts
hickory nuts
nectarines
olives
peaches
pears
pecans
persimmons
pineapple
plums
pomegranates
prunes
quince
walnuts

Bush and Vine Planting Sites:

blackberries
blueberries
boysenberries
cranberries
currants
dewberries
gooseberries
grapes
huckleberries
loganberries
raspberries
strawberries
youngberries

General Warnings and Limitations (continued)

Nursery Crops: including floral plants, ornamentals, shrubs and bushes, forest, shade, fruit and nut trees and vine and bramble fruits of all types.

APPLICATION DIRECTIONS:
When to Treat: Apply Telone II either in the spring, or fall, whenever soil type and conditions permit. For best results with annual crops, treat the soil each year. In northern states, late summer, or early fall treatment (before October 15) is best for land to be planted to early spring crops, especially transplanted crops such as celery, tomatoes, and nursery and orchard stock. Early fall treatment permits planting a fall cover crop. Note: Treat muck soils only in the early fall and plant as late as possible in the spring; treat fine textured (clay) soils only when they are near or at the wilting point. Do not use Telone II to treat any type of soil when it is cold and/or wet.
Soil Preparations: Telone II gives best results when conditions permit rapid diffusion of the fumigant through the soil and the soil surface can be sealed to prevent excessive fumigant loss during the exposure period. The soil should be in good seed bed condition, free of clods and undecomposed plant material, moisture at about one-half of field capacity, and temperature between 40 and 80 F (4.4 and 26.7 C) at the depth of injection. If undecomposed plant debris is present, it should be plowed down and allowed to decompose before applying Telone II. Tillage deeper than 12 inches is necessary for good fumigant penetration in soils where a hard or "plow" pan occurs at plow depth. Where deep tillage is used, the tillage equipment may often be modified to simultaneously apply the fumigant and thus avoid going over the field twice.
Application: Telone II may be applied either as a broadcast (overall) or row treatment, using suitable application equipment that will ensure placement of the fumigant at least 6 to 8 inches below the final soil surface. For broadcast application, use either plowsole or chisel equipment with the chisels spaced 12 inches apart. When the fumigant is injected at a depth of 12 inches or more (deep tillage), the chisel spacing may be up to twice the application depth but should not exceed 30 inches. Application may be made in the same direction or at an angle to the direction of the planting row, whichever is most convenient. For row application, use chisel equipment with 1 chisel per row or 2 chisels spaced 12 inches apart to treat only the soil where the crop is to be planted. When 1 chisel per row is used, adjust the fumigant flow rate to distribute about 1.33 times more fumigant per chisel than is recommended for overall application. When 2 chisels are used per row, apply at the same flow rate per chisel as for broadcast. In both cases, the amount of fumigant required per acre will decrease as the distance between rows is increased and vice versa. At time of planting, avoid placing the seed row directly over the furrow left by the applicator chisel. When a single chisel is used per row, place the seed 3 to 4 inches to 1 side of the chisel furrow; when 2 chisels are used, plant in the center of the area between the chisel furrows.

General Warnings and Limitations (continued)

Sealing: Immediately after application, compact the soil surface to prevent excessive fumigant loss. After chisel application, use a roller, cultipacker, or similar sealing device. After plow-side application, disk the land, then compact it by floating or rolling. Sealing after row application can be accomplished by the tractor wheel, by listing, or by bedding so that the fumigant will be 12 to 14 inches below the top of the bed. When fumigating listed rows, seal in the fumigant with ring rollers, press sealers, or by re-listing.

Exposure Period: After application and sealing, leave the soil undisturbed for 7 to 14 days. A longer exposure period will be required if the soil becomes excessively cold or wet during the exposure period.

Aeration and Preparation of Soil Before Planting: At the end of the exposure period allow the soil to aerate completely before planting the crop. Aeration is usually complete when the odor of Telone II is no longer evident. Under optimum soil and weather conditions, allow 1 week of aeration time for each 10 gallons of Telone II applied per acre. When Telone II is used for treating deep-rooted tree and shrub planting sites, a 3 to 6 months aeration period should be allowed. To hasten aeration, especially if heavy rains or low temperatures occur during the exposure period, work the soil to the depth of the treatment zone. After row treatment use a knife-like chisel in the bed without turning the soil, thus reducing possible recontamination of the treated soil. To hasten aeration after overall treatment, plow or deep cultivate to the depth of the treatment zone. This is especially desirable in northern states after fall fumigation of muck soils.

Note: To avoid reinfestation of treated soil do not use irrigation water, transplants, tools, seed pieces or crop remains that could carry soilborne pests from infested land. Clean equipment carefully before using.

Note: Dosages are given in pounds active ingredient.

EPA Compendium of Acceptable Uses

1,3-DICHLOROPROPENE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01001AA /02000AA /28038AA /03000AA /28043AA /30000AA /35000AA /32000AA /26003AA	Caneberries Citrus Fruits Deciduous Fruit Trees Nut Trees Vine Fruits		N.F. Preplant soil treatment through 313.5 pounds per acre for sandy soil, 456.0 pounds per acre for sandy loam, 712.5 pounds per acre for silt loam, and 969.0 pounds per acre for clay loam.
NABAAAA IJDAAAA INAVAAA	Nematodes Symphylans Wireworms		Preplant soil treatment. Broadcast. Apply to nursery and field planting sites.

Pounds a.i. (94% RTU) per acre to penetrate various depths

Mineral soils	3 ft	4 ft	5 ft	6 ft
sand	142.5	199.5	256.5	313.5
sandy loam	256.5	285.0	342.0	456.0
silt loam	399.0	434.5	598.5	712.5
clay loam	513.0	655.5	798.0	969.0

		1.94 lb/hole (94% RTU)	Preplant soil treatment to tree planting sites prepared by backhoeing. Apply by pouring into the hole during backfilling. For best results prepare and treat sites in the fall and plant in the spring.

Refer to Citrus Fruits for additional information.

/02000AA	Citrus Fruits		N.F. Preplant soil treatment through 342.0 pounds per acre in FL.
NEJBCBA NABAAAA IJDAAAA INAVAAA	Burrowing nematode Nematodes Symphylans Wireworms	Broadcast: 342.0 lb/A or 7.87 lb/1,000 linear ft of row/chisel (94% RTU)	Use limited to FL. Preplant soil treatment. Apply as a broadcast treatment on mineral soils. For burrowing nematode, inject on 18-inch centers, 12 inches deep. Keep area free of plants that are susceptible to burrowing nematodes for 2 years before replanting to citrus.

Also refer to Caneberries cluster for additional information.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Deciduous Fruit Trees		See Caneberries cluster.
/28049AA /01000AA /28024AA /31003AA /33011AA /32000AA /33008AA	Field Crops Small Fruits Vegetables		N.F. Preplant soil treatment through 331.2 pounds per acre in muck or peat soils or 165.8 pounds per acre in mineral soils using broadcast treatment; or, 110.4 pounds per acre in muck or peat soils or 55.2 pounds per acre using row treatment on 42 inch spacing. Row treatment is not recommended for potatoes in irrigated areas of western and northwestern states.
NEFBAAA NABAAAA IJDAAAA INAVAAA	Cyst nematodes Nematodes Symphylans Wireworms	Broadcast: 85.5-171.0 lb/A or 1.93-3.93 lb/1,000 linear ft of row/ chisel [mineral] or 171.0-342.0 lb/A or 3.93-7.87 lb/1,000 linear ft of row/ chisel [muck or peat] or Row (42 inch spacing): 42.75-57.0 lb/A or 3.41-4.6 lb/1,000 linear ft of row/ chisel [mineral] (94% RTU) or	Preplant soil treatment for shallow rooted plants. Apply the higher rates in heavier soil. For symphylans, use only the broadcast treatment at a minimum of 171.0 pounds per acre, and apply during late summer or early fall when the soil is warm. For wireworms, apply the higher rates recommended for nematodes in broadcast treatments. For broadcast treatment of cyst-forming nematodes in mineral soils, apply 171.0 pounds per acre; for other nematodes, apply up to 142.5 pounds per acre. For broadcast treatment of muck soils containing less than 30 percent organic matter, apply 171.0 pounds per acre; otherwise, apply a minimum of 228.0 pounds per acre.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Field Crops cluster (continued)		
		85.5-114.0 lb/A or 6.9-9.13 lb/1,000 linear ft of row/ chisel [muck or peat] (94% RTU)	
/28012AA	**Mint**		N.F. Preplant soil treatment through 560.5 pounds per acre (broadcast).
FGATVAK	Verticillium wilt	Broadcast: 560.5 lb/A or 12.84 lb/ 1,000 linear ft of row/ chisel (94% RTU)	Use limited to northwestern states. Preplant soil treatment. Apply to aid in the reduction of the effects of Verticillium wilt in disease infested soil. Apply in the spring or preferably in the fall. After treatment allow at least 7 to 8 weeks or until the odor of the fumigant has left the soil before planting. Consult a State Cooperative Agricultural Extension Service for the use of other practices such as flaming the stubble, weed control, and cultural practices when using the active ingredient as an aid to reducing damage caused by Verticillium wilt.
		Refer to Field Crops cluster for additional information.	
	Nut Trees		See Caneberries cluster.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/05004AA	Peach		N.F. Preplant soil treatment through 342.0 pounds per acre (broadcast).
FDZAPDZ	Bacterial canker (Pseudomonas)	Broadcast: 228.0-342.0 lb/A or 5.27-7.87 lb/1,000 linear ft of row/chisel (94% RTU)	Preplant soil treatment. Apply as an aid in the control of bacterial canker and decline in light (sandy) soils. Apply preferably in the fall when the soil is warm (50 to 85 F (10.0 to 29.4 C) at 6-inch depth) and moist. Inject at a depth of 10 to 12 inches with chisels mounted on 12 inch centers.
		Refer to Caneberries cluster, Deciduous Fruit Trees for additional information.	
/06013AA	Pineapple		N.F. Preplant soil treatment through 342.0 pounds per acre (broadcast).
NABAAAA IJDAAAA INAVAAA	Nematodes Symphylans Wireworms	Row: 228.0-342.0 lb/A [mineral] (94% RTU)	Preplant soil treatment. For Hawaiian pineapple, apply at time of or just before planting.
/14013AA	Potato (white)		N.F. Preplant soil treatment through 237.5 pounds per acre in the spring, or 323.0 pounds per acre in the fall.
PCAACBA FGATVAK	Quackgrass Verticillium wilt [suppression]	Broadcast: Spring - 161.5-237.5 lb/A or 3.71-5.42 lb/1,000 linear ft of row/chisel or Fall - 237.5-323.0 lb/A (94% RTU) or	Use limited to northwestern states. Preplant soil treatment. Apply in the spring or preferably in the fall.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Potato (white) (continued)		
		5.42-7.42 lb/1,000 linear ft of row/ chisel (94% RTU)	
		Also refer to Field Crops cluster for additional information.	
	Small Fruits		See Field Crops cluster.
/01016AA	Strawberry		N.F. Preplant soil treatment through 342.0 pounds per acre (broadcast).
NABAAAA IJDAAAA INAVAAA	Nematodes Symphylans Wireworms	Broadcast: 228.0-342.0 lb/A or 5.27-7.87 lb/1,000 linear ft of row/ chisel (94% RTU)	Preplant soil treatment. Apply as a broadcast treatment on mineral soil.
/28020AA	Sugar Beets		N.F. Preplant soil treatment through 171.0 pounds per acre (broadcast) or 85.5 pounds per acre (42 inch row spacing).
NEOBCAA	Root-knot nematode	Broadcast: 114.0-142.5 lb/A or 2.6-3.265 lb/1,000 linear ft of row/ chisel or Row: 57.0 lb/A (94% RTU) or	Preplant soil treatment. Apply as specified on mineral soils.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Sugar Beets (continued)		
		4.6 lb/1,000 linear ft of row/chisel [42 in. row spacing] (94% RTU)	
NEFBCBB	Sugar beet cyst nematode	Broadcast: 114.0-171.0 lb/A or 2.6-3.93 lb/1,000 linear ft of row/chisel or Row: 85.5 lb/A or 6.9 lb/1,000 linear ft of row/chisel [42 in. row spacing] (94% RTU)	Preplant soil treatment. Apply as specified on mineral soils.
	Vegetables		See Field Crops cluster.
	Vine Fruits		See Caneberries cluster.
	TERRESTRIAL NON-FOOD CROP		
	(Agricultural Crops)		
	Tobacco	See TERRESTRIAL FOOD CROP, (Agricultural Crops), Field Crops cluster.	
	(Ornamental Plants and Forest Trees)		
/30000DA	Forest Trees		
/35000AA	Ornamental and/or Shade Trees		
/32000AA	Ornamental Plants (deep rooted)		
		Refer to TERRESTRIAL FOOD CROP, (Agricultural Crops), Caneberries cluster.	

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

/31003AA Ornamental Flowering Plants
/33011AA Ornamental Grasses
/32000AA Ornamental Plants
/33008AA Ornamental Turf

Refer to TERRESTRIAL FOOD CROP, (Agricultural Crops), Field Crops cluster.

Listing of Registered Pesticide Products by Formulation

&292.0016 94% (9.5 lb/gal) liquid-ready to use

1,3-dichloropropene (029001)

000464-00511 000550-00103 000912-00079 001202-00308*
001526-00503* 006023-00035 006735-00237 007729-00006
008399-00006 008526-00004 008773-00017 009018-00004
010226-00054 011220-00001 011656-00064 011682-00025
011684-00003 035296-00001 035550-00001 035552-00001
036020-00001 037177-00001

*currently unavailable for review

9999999 State Label Registrations

CA Reg. No.
002935-06588 011079-04801 011261-06187

CO Reg. No.
008773-06231

HI Reg. No.
000464-07105

ID Reg. No.
008917-05583 0914-09516

MT Reg. No.
011682-06252

NB Reg. No.
008917-06251 011684-08187

OR Reg. No.
002935-06628 010914-09515 011261-06188

TX Reg. No.
006735-05393

WA Reg. No.
003826-05834

WY Reg. No.
011684-08188